

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/007674

International filing date (day/month/year)
12.07.2004

Priority date (day/month/year)
15.07.2003

International Patent Classification (IPC) or both national classification and IPC
A23L 1/29, A23L 1/052, A23L 1/308

Applicant
NESTEC S.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/564452
International application No.
PCT/EP2004/007674

IAP20 Rec'd PCT/EP 12 JAN 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/007674

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
Industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-15
Inventive step (IS)	Yes: Claims	
	No: Claims	1-15
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/007674

Re Item V.

Cited documents

- 1 The following documents are referred to in this communication:
D1 : WO 02/39834 A (SCHIFFRIN EDUARDO ;SPIVEY KROBATH EVELYN
(CH); NESTLE SA (CH); CAV) 23 May 2002 (2002-05-23)
D2 : US 2003/104033 A1 (LAI CHON-SI ET AL) 5 June 2003 (2003-06-05)
D3 : EP 0 721 742 A (CLINTEC NUTRITION CO) 17 July 1996 (1996-07-17)
D4 : EP 0 756 828 A (NUTRICIA NV) 5 February 1997 (1997-02-05)
D5 : US 6 200 950 B1 (MICHALSKI TOM ET AL) 13 March 2001 (2001-03-13)
D6 : WO 99/53777 A (CLAYTON DIANE ELIZABETH ;NOVARTIS NUTRITION
AG (CH); LUSTENBERGER) 28 October 1999 (1999-10-28)
D7 : US 4 833 128 A (SOLOMON NEIL ET AL) 23 May 1989 (1989-05-23)
D8 : WO 03/053165 A (NAVARRO Y KOREN PETER ANTONIO ; NUTRICIA NV
(NL); MINOR MARCEL (NL); D) 3 July 2003 (2003-07-03)
D9 : EP 1 314 362 A (SAMADHI BIOCYBERNETICS GMBH) 28 May 2003
2003-05-28)

Clarity

- 2 The following clarity deficiencies were noted (Art. 6 PCT).
 - 2.1 A clarity problem arises from the wording of claim 1, as a powder is normally not measured in "ml". It is not unambiguously clear how to interpret a powdered composition having a definite energy density of .../ml and a dietary fibre content of .../100ml.
 - 2.2 Any composition having a ratio of 130-180 kcal per 2.5 g or more of dietary fibre is suitable to be reconstituted to the liquid disclosed in claim 1.
 - 2.3 The subject-matter of claim 6 is unclear, as a powder does not have a viscosity.
 - 2.4 The subject-matter of product claims 10-12 is considered to be related to non-therapeutic products. The same applies mutatis mutandis to the subject-matter of method claims 14 and 15.
 - 2.5 Following PCT-Guideline 5.23 the subject-matter of claims 10-12 will be interpreted as products suitable for providing the desired effect. In a claim directed to a product, features concerning its use are normally disregarded. A novel use of a composition does not make the composition as such novel.
 - 2.6 The subject-matter of claim 1 is not supported by p.3 §2.

Novelty

- 3 The subject-matter of independent product claim 1 and of independent method claims 13-15 does not fulfil the requirements of Art.33(2) PCT.
- 3.1 D1 renders available to the one skilled in the art compositions suitable for elderly patients and for restoration of gut integrity having 1.6 kcal/ml and up to 16.6g dietary fibres /100ml (claim 11; Example 1; p.1 l.1-p.3 l.7).
- 3.2 D6 discloses in Example 3 powdered compositions having a ratio of up to 0.18kcal each 2.5mg dietary fibre.
- 3.3 D7 (Example 1; col.2 l.1-18) discloses a dry food product which can be reconstituted to a drink, the dry food product comprising protein sources, carbohydrate sources, a fat source and dietary fibre in an amount of 2.5g per 167kcal. The viscosity of the reconstituted product is considered to be implicitly between 30-80 mPas.
- 3.4 D8 discloses a dry food product which can be reconstituted to a drink, the dry food product comprising protein sources, carbohydrate sources, a fat source and dietary fibre in an amount of more than 2.5g per 130kcal (p.7 l.6-p.8 l.3; examples 2 and 3). The viscosity of the reconstituted product is considered to be implicitly between 30-80 mPas.
- 3.5 D9 (Examples 1 and 2) discloses a dry food product which can be reconstituted to a drink, the dry food product comprising protein sources, carbohydrate sources, a fat source and pea dietary fibre in an amount of 2.5g per 176kcal. The viscosity of the reconstituted product is considered to be implicitly between 30-80 mPas.

Inventive step

- 4 The subject-matter of presently claimed does not involve an inventive step (Art.33(3) PCT).
- 4.1 D3 and D4 disclose independently from each other compositions having up to 1.8kcal/ml. The subject-matter of the present application differs only in that the dietary fibre content according to the present application is higher than the one disclosed in D3 and D4.
- 4.2 The objective problem is to provide compositions for the elderly providing good gut function.
- 4.3 In the first place it is known that the solution is provided by increasing the amount of dietary fibre. The idea of increasing the amount of dietary fibre is therefore not inventive, on the contrary, it appears to be rather a desideratum.
- 4.4 Additionally, D5 suggests the use of dietary fibres in fluid composition in an

amount up to 12g/100ml (claim 9) for providing good functioning of the guts (col.1 l.1-col.2 l.31). The mixture of fibres to be used comprise oligosaccharides, soluble and non-soluble fibres in the amounts given in claims 1-4.

- 4.5 Similarly, in view of D2, a document disclosing complete fluid nutritional compositions containing up to 35g of fibres/L ([0002]-[0019] and [0050]-[0054]) the subject-matter does not appear to be inventive. D2 describes use of carboxymethyl cellulose, FOS, Fibrim, gum arabic and oat fibre (see table 4).
- 4.6 At present, the subject-matter of the depending claims is not considered to involve an inventive step.

Re Item VII

Certain defects in the international application

- 1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D9 is not mentioned in the description, nor are these documents identified therein.